



7/15/98

NOTIFICATION PURSUANT TO

SECTION 6 OF DSHEA
AND 21 CFR §101.93 05 '98 AUG -5 P1:41

This notification is being filed on behalf of 4Health, Inc., doing business as Harmony Formulas®, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **B Formula**.

The text of each structure-function statement for which notification is now being given is:

- Statement 1. Because stress, illness, injury, processed food, and stimulants such as caffeine, alcohol, sugar and tobacco may increase the body's need for the essential B-vitamins, Ultimate B is a helpful step towards optimum nutrition.
- Statement 2. B vitamins work in the body to help convert proteins, carbohydrates and fats into fuel, and in the brain to help synthesize the mood controlling chemicals.
- Statement 3. B vitamins are integral to nervous system support.
- Statement 4. Many individuals who complain about fatigue and low energy levels experience remarkable improvements after supplementing their diets with B complex vitamins.
- Statement 5. Users notice enhanced energy levels, enhanced mental clarity, improved overall endurance and general health.
- Statement 6. Supports and nourishes the central nervous system.
- Statement 7. Helps to form collagen, aids in the absorption of vitamins B6 and B12, and supports the immune system.
- Statement 8. Improves mental function, needed for energy production in the brain, and the metabolism of carbohydrates.
- Statement 9. Needed for the production of energy and a component in the formation of important protectors from free radical damage.
- Statement 10. Essential for proper functioning of many enzymes throughout the body, healthy skin, immune system, and brain function.
- Statement 11. Essential to cellular division, fetal development, and DNA synthesis.
- Statement 12. Essential for proper nerve and immune function and energy metabolism.
- Statement 13. Involved in the breakdown of glucose and fatty acids to be used as energy, cell growth, and promotes healthy skin, hair and nails.
- Statement 14. Important component of fat and carbohydrate metabolism and the production of adrenal hormones and red blood cells.
- Statement 15. Essential for proper brain, muscle and nerve function. Has shown to have lipotropic effects which support the health of the liver.
- Statement 16. Supports brain function, may improve memory, and involved in the metabolism of fats from the liver.
- Statement 17. Important in protein metabolism, promotes healthy hair and skin.
- Statement 18. Traditionally used as a general preventative and tonic. It is an adaptogen and is effective for stress control. Siberian Ginseng has been shown to increase mental alertness.
- Statement 19. Traditionally used to support the liver and kidney and acts as a blood purifier.
- Statement 20. Used in Ayurvedic medicine to assist in the absorption and utilization of nutrients included the B vitamins in this formula.
- Statement 21. Proteolytic and anti-inflammatory enzyme.

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- Statement 22. Strengthens digestion, supports the adrenals helping to counteract stress.
 Statement 23. Enzyme for fat digestion.
 Statement 24. Enhances the absorption of some B vitamins.
 Statement 25. Contains enzymes that stimulate the secretion of digestive fluids which help to support the digestion and assimilation of B vitamins in the formula more efficiently.
 Statement 26. Acts as a catalyst stimulating the digestion and transport of the B vitamins to parts of the body where they are needed.
 Statement 27. Essential in the synthesis of ATP, energy required for the body's processes.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

Statement Number	Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement
1	Vitamin B ₁ (Thiamin), Vitamin B ₂ (Riboflavin), Vitamin B ₅ (Pantothenic Acid), Vitamin B ₆ (Pyridoxine), Vitamin B ₁₂ (Cobalamin),
2	Vitamin B ₁ (Thiamin), Vitamin B ₂ (Riboflavin), Vitamin B ₅ (Pantothenic Acid), Vitamin B ₆ (Pyridoxine), Vitamin B ₁₂ (Cobalamin),
3	Vitamin B ₁ (Thiamin), Vitamin B ₂ (Riboflavin), Vitamin B ₅ (Pantothenic Acid), Vitamin B ₆ (Pyridoxine), Vitamin B ₁₂ (Cobalamin),
4	Vitamin B ₁ (Thiamin), Vitamin B ₂ (Riboflavin), Vitamin B ₅ (Pantothenic Acid), Vitamin B ₆ (Pyridoxine), Vitamin B ₁₂ (Cobalamin),
5	Vitamin B ₁ (Thiamin), Vitamin B ₂ (Riboflavin), Vitamin B ₅ (Pantothenic Acid), Vitamin B ₆ (Pyridoxine), Vitamin B ₁₂ (Cobalamin),
6	Vitamin B ₁ (Thiamin), Vitamin B ₂ (Riboflavin), Vitamin B ₅ (Pantothenic Acid), Vitamin B ₆ (Pyridoxine), Vitamin B ₁₂ (Cobalamin), Kelp, Siberian Ginseng Extract, Alfalfa Leaf, Shattered Cell Wall Chlorella, Licorice Root, Acerola Berry, Rosehips, Ginger Root, Capsicum Fruit
7	Vitamin C
8	Vitamin B ₁ (Thiamin)
9	Vitamin B ₂ (Riboflavin)
10	Vitamin B ₆ (Pyridoxine)
11	Folic Acid
12	Vitamin B ₁₂ (Cobalamin)
13	Biotin
14	Pantothenic Acid
15	Inositol
16	Choline
17	PABA (para-aminobenzoic acid)
18	Siberian Ginseng Extract
19	Alfalfa Leaf

20	Triphala Powder
21	Bromelain
22	Papain
23	Licorice Root
24	Acerola Berry
25	Ginger Root
26	Capsicum Fruit

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	Nature's Secret® Ultimate B	Both
2	Nature's Secret® Ultimate B	Labeling
3	Nature's Secret® Ultimate B	Labeling
4	Nature's Secret® Ultimate B	Labeling
5	Nature's Secret® Ultimate B	Labeling
6	Nature's Secret® Ultimate B	Labeling
7	Nature's Secret® Ultimate B	Labeling
8	Nature's Secret® Ultimate B	Labeling
9	Nature's Secret® Ultimate B	Labeling
10	Nature's Secret® Ultimate B	Labeling
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25	Nature's Secret® Ultimate B	Labeling
26	Nature's Secret® Ultimate B	Labeling

I, R. Lindsey Duncan, am authorized to certify this Notification on behalf of 4Health, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that 4Health, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: June 30, 1998

By: R. Lindsey Duncan

Dr. R. Lindsey Duncan CN, ND
CEO and Formulator, 4Health, Inc.